K070606

Keosys
TECHNOLOGIES DE L'INFORMATION

APR 24 2007

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for Visio+ CD Viewer in conformance with 21 CFR 807.92

Date Prepared: January 2007.

Submitter:
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Contact name: Mr. Anthony Mottier
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Device Trade Name: Visio+ CD Viewer
Device Common Name: DICOM CD Viewer
Device Classification Name: Picture Archiving and Communication System
Classification Panel: 21 CFR §892.2050
Product code: LLZ
Device Classification: Class II

Predicate Device Name: MIMviewer
Predicate Device Manufacturer: MIMvista Corp.
Predicate Device 510(k) number: K062163

Device Description:

Visio+ CD Viewer is a component software which must be burned on a CD-ROM with medical images by another Medical Device.
Visio+ CD Viewer operates only on a computer that meets the following requirements: Windows 2000/XP, Pentium III 1 GHz or better, 512 Mo RAM, minimum display resolution 1024x768, a CD or DVD drive.
Visio+ CD Viewer provides tools for image review and manipulation.

Indications for Use:

Visio+ CD Viewer is a software component that is used for viewing medical images stored on a CD-ROM. This software is not meant for primary image interpretation in mammography. Visio+ CD Viewer is located on the CD-ROM with the medical images. Visio+ CD Viewer provides tools for image review and manipulation which can only be used with the medical images present on the CD-ROM. Typical users of Visio+ CD Viewer are trained professionals, including physicians and radiologists.

Testing:

Visio+ CD Viewer is tested according to the specifications that are documented in a Software Test Plan. Performance and functional testing are an integral part of Keosys's software development process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Mottier Anthony
System Quality Manager
Keosys S.A.S.
1, impasse Augustin Fresnel, Z.A. duMoulin Neuf
Saint-Herblain, 44815
FRANCE

APR 24 2007

Re: K070606
Trade/Device Name: Visio+ CD Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 15, 2007
Received: March 5, 2007

Dear Mr. Anthony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Visio+ CD Viewer.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070606